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21 UNITED STATES DISTRICT COURT  
22 SOUTHERN DISTRICT OF CALIFORNIA



23 GEN-PROBE INCORPORATED,

24 Plaintiff,

25 v.

26 VYSIS, INC.,

27 Defendant.

No. 99CV2668H AJB

**[PROPOSED] SECOND AMENDED COMPLAINT  
FOR DECLARATORY RELIEF AND UNFAIR  
COMPETITION**

28 PLAINTIFF GEN-PROBE ALLEGES:

**INTRODUCTION**

1. This action concerns the nature and scope of any obligation of plaintiff Gen-Probe Incorporated ("Gen-Probe") to make royalty payments to defendant Vysis, Inc. ("Vysis") pursuant to a patent license agreement between the parties ("the License") in light of the invalidity and non-infringement of United States Patent No. 5,750,338 ("the '338 patent") that is a subject of that

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1 License. As set forth below, Gen-Probe asks this Court to declare the '338 patent invalid and  
2 further to declare that Gen-Probe's current and anticipated activities do not infringe any valid  
3 claims of the '338 patent. As a corollary to those declarations, Gen-Probe also asks this court to  
4 declare its rights and obligations under the terms of the parties' License. Finally, Gen-Probe also  
5 seeks relief from Vysis' continuing acts of wrongful and unfair conduct with respect to the '338  
6 patent.

#### 7 THE PARTIES

8 2. Gen-Probe was founded in San Diego in 1984 as a small "start up" company,  
9 seeking to develop products based on the discoveries of a local research scientist. Over time, Gen-  
10 Probe became one of the largest biotechnology firms in San Diego. Gen-Probe now maintains its  
11 principal offices and research facilities at 10210 Genetic Center Drive in San Diego, where it  
12 employs over 500 scientists and staff. Gen-Probe is organized under the laws of the State of  
13 Delaware.

14 3. Gen-Probe is informed and believes that defendant Vysis, Inc. (hereinafter "Vysis"  
15 or "the defendant") is a corporation organized and incorporated under the laws of the State of  
16 Delaware. Gen-Probe is further informed and believes that Vysis maintains its principal place of  
17 business in Downers Grove, Illinois and that it is controlled by BP Amoco, Inc.

#### 18 JURISDICTION AND VENUE

19 4. Counts One and Two of this Complaint seek declaratory relief under the  
20 Declaratory Judgment Act, Title 28, United States Code, Sections 2201 and 2202. This Court has  
21 subject matter jurisdiction of the claims asserted thereunder by reason of Title 28, United States  
22 Code, Sections 1331, 1338(a), 1338(b) and 1367.

23 5. Venue is proper in this District under Title 28, United States Code, Sections  
24 1391(b) and 1400(b).

#### 25 BACKGROUND

26 6. Living cells store genetic information in molecules of nucleic acid known as DNA.  
27 These molecules consist of long, thin, chain-like strands which, in turn, are usually found in the  
28 form of two tightly bound, complementary chains. DNA molecules retain their genetic information



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11. At the time of the NIH grant to Gen-Probe, donated blood was principally tested by procedures that detected the presence of antibodies to the viruses being screened. Due to the time it takes for the body to make antibodies after initial infection, donated blood may test negative for antibodies, yet still carry infectious viruses. This delay between the time of actual infection and the time that antibodies can first be detected is often known as the "window period." Reduction of this "window period" was a significant concern of the United States government and the primary focus of the grant to Gen-Probe to develop NAT diagnostics for use in blood screening.

12. In fulfilling its obligations under the grant, Gen-Probe developed NAT tests to detect the DNAs of HIV and hepatitis C in blood. Through the use of its NAT test, Gen-Probe believes that researchers and medical personnel may rapidly and *directly* detect the presence of genetic material of viruses like HIV and HCV more accurately and without the complications and delay associated with conventional *indirect* tests. As such, Gen-Probe believes that its new test may significantly reduce the "window period" for detection of these extremely harmful viral agents and resulting diseases.

13. Final development of the NAT tests for blood screening in the United States is now taking place in testing conducted by the American Red Cross, America's Blood Centers, and others. ("A Purity Quest; Local Biotech's Ultra-Sensitive Blood Screening Could Cut Risk of AIDS, Hepatitis," *San Diego Union*, March 25, 1999, page C-1.) Use of the tests in the United States is made pursuant to an Investigational New Drug Application filed with the United States Food and Drug Administration. In blood tested by the American Red Cross, Gen-Probe's products have detected hepatitis C and HIV which escaped detection by prior methods. ("New Blood Screening Finds Virus Others Missed; Experimental Test Turns Up Hepatitis C In Donated Blood," *San Diego Union*, April 2, 1999, page B-2.)

14. On September 21, 1999, the French Ministry of Health approved the sale of the Gen-Probe blood screening tests in France. Gen-Probe anticipates approval of its tests for use in Australia in early 2000.

15. Gen-Probe has entered into an agreement with Chiron Corporation ("Chiron") of Emeryville, California, with respect to the development, manufacture, and distribution of blood



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1 As such, Gen-Probe disagrees with Vysis' contention that the claims of the '338 patent "apply" to  
2 Gen-Probe's activities and contemplated products. For these same reasons, Gen-Probe contends  
3 that it has no obligation to make any royalty payments to Vysis with respect to its present products  
4 and activities and any contemplated products and activities that Vysis may later claim infringe the  
5 claims of the '338 patent.

6 23. Gen-Probe has communicated to Vysis its belief that the claims of the '338 patent  
7 are invalid. In support of that belief, Gen-Probe has provided Vysis with information that  
8 demonstrates that the claims of the '338 patent are invalid. Gen-Probe has also advised Vysis of its  
9 belief that its NAT test kits for use in detecting HCV and HIV in the Nation's blood supply do not  
10 and will not infringe any valid claims of the '338 patent.

11 24. Notwithstanding its receipt of the foregoing information, Vysis persists in its  
12 assertion that the claims of the '338 patent are valid and enforceable and that Gen-Probe is  
13 obligated to make royalty payments in accordance with the terms of the License.

14 25. Based upon a long history of litigation between Gen-Probe and Vysis and its  
15 affiliates, Gen-Probe reasonably anticipates that should it fail to pay royalties pursuant to the  
16 License, Vysis will aggressively attempt to enforce its perceived rights under both the License and  
17 the '338 patent by terminating the License and by initiating litigation against Gen-Probe, its allied  
18 parties, and customers.

19 26. An actual case or controversy exists between Gen-Probe and Vysis concerning the  
20 validity and infringement of the '338 patent and Gen-Probe's rights and obligations under the  
21 License. The determination of the issues presented in this complaint will inure to the greater public  
22 benefit and good.

23 COUNT ONE

24 NON-INFRINGEMENT OF THE '338 PATENT

25 27. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1  
26 through 26 of this complaint.

27 28. Gen-Probe's NAT test kits for use in detecting HCV and HIV in the Nation's blood  
28 supply do not and will not infringe any valid claims of the '338 patent.

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COUNT TWO

INVALIDITY OF THE '338 PATENT

29. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 26 of this complaint.

30. The claims of the '338 patent are invalid by reason of one or more provisions of Title 35 of the United States Code.

COUNT THREE

DECLARATORY RELIEF

31. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 26 of this complaint.

32. An actual controversy has arisen and now exists concerning the rights and obligations of Gen-Probe pursuant to the terms of the parties' License. Those disputes arise from and their resolution depends upon the federal patent laws.

33. Gen-Probe seeks a declaration of its rights and obligations under the License, particularly in light of the invalidity and non-infringement of the '338 patent and defendant's acts of unfair competition as alleged herein.

COUNT FOUR

UNFAIR COMPETITION

34. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 33 of this complaint.

35. Vysis knows or should know the underlying facts establishing the invalidity and/or unenforceability of the claims of the '338 patent. In continuing to enforce the claims of the '338 patent, Vysis has acted and continues to act unfairly, inequitably and in bad faith. In addition, Vysis' actions constitute unlawful, unfair or fraudulent business practices under California Business & Professions Code Sections 17200, *et seq.*

36. By reason of the aforementioned acts of unfair competition and unlawful, unfair and fraudulent business practices, Gen-Probe is entitled to damages, as established at time of trial,



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1 restitution and injunctive relief.

2 COUNT FIVE

3 UNENFORCEABILITY OF THE '338 PATENT

4 37. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1  
5 through 36 of this complaint.

6 38. Applicants for patents have a general duty of candor and good faith in their dealings  
7 with the Patent and Trademark Office (the "Patent Office") and an affirmative obligation to disclose  
8 to the Patent Office all information that they know to be material to the examination of a pending  
9 application pursuant to 37 C.F.R. § 1.56. This duty extends to the applicants and their  
10 representatives, such as their attorneys, and all others associated with the prosecution, including  
11 every person who is substantively involved in the preparation or prosecution of the application.

12 39. Gen-Probe is informed and believes, and thereon alleges, that Vysis or its  
13 predecessors-in-interest and their agents (hereinafter collectively referred to as "the applicants")  
14 knowingly and willfully concealed and misrepresented material evidence during the prosecution of  
15 the '338 patent applications and that by such inequitable conduct, the '338 patent is unenforceable  
16 against Gen-Probe for the reasons that follow.

17 **FACTS RELATED TO THE ABANDONMENT OF THE CLAIMED INVENTION OF**  
18 **NUCLEIC ACID AMPLIFICATION**

19 40. On October 23, 1986, the applicants filed a patent application entitled "Target and  
20 Background Capture Methods and Apparatus for Affinity Assays." After filing, the Patent Office  
21 assigned that application the numerical designation, Serial No. 06/922,155 (the "'155 application").  
22 Although, the '155 application purported to describe a technique for reversible target capture, it  
23 contained no disclosure of or claims to amplification techniques as claimed by Vysis in the '338  
24 patent. The applicants identified Mark L. Collins as the sole inventor of the alleged inventions  
25 claimed in the '155 application.

26 41. On December 21, 1987, prior to substantive examination of the '155 application by  
27 the Patent Office, Vysis filed a Continuation-in-Part of the '155 application. The Patent Office  
28 assigned this Continuation-in-Part application Serial No. 07/136,920 (the "'920 application"). The





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1 application by which they elected to prosecute only instrument-related claims originally presented  
2 as claim 24 of the '920 application. The Patent Office assigned this instrument application Serial  
3 No. 07/648,468 (the "'468 application"). As originally filed and consistent with the restriction  
4 requirement, in the '468 application, the applicants submitted only claims directed to an instrument  
5 for performing assays for target polynucleotides. The applicants entitled the '468 application  
6 "Closed Vessel for Isolating Target Molecules and for Performing Amplification."

7 52. Through their '468 application, the applicants claimed priority of their instrument  
8 invention as a continuation-in-part application to the '920 and earlier '155 applications. However,  
9 applicants' claim to priority to the '920 and '155 applications was defective as it violated the  
10 requirement that the '468 application have been filed prior to the abandonment of the priority  
11 applications. In this case, although the applicants filed the '468 application on January 31, 1991,  
12 they intentionally abandoned the '920 application on January 22, 1991 and intentionally abandoned  
13 the '155 application on February 3, 1990. The applicants intentionally failed to disclose this lack of  
14 co-pendency of the '468 application during the prosecution of the '468 application.

15 53. The Patent Office initially rejected all the claims of the '468 application on prior art  
16 and other grounds of patentability in an office action mailed March 18, 1992. The Patent Office  
17 provided the applicants until June 18, 1992, with extensions available until September 18, 1992, to  
18 submit a substantive response to that office action.

19 54. Rather than prepare a substantive response to the March 18, 1992 office action, and  
20 in order to continue prosecuting claims to an instrument for performing assays for target  
21 polynucleotides, on September 17, 1992, the applicants filed a continuing application from the '468  
22 application. The Patent Office designated this continuing application as application Serial No.  
23 07/946,749 (the "'749 application"). Consistent with the restriction requirement originally issued  
24 in the '920 application, the applicants submitted only claims directed to an instrument for  
25 performing assays for target polynucleotides in the '749 application. Concurrent with the filing of  
26 the '749 application, the applicants then expressly abandoned the '468 application.

27 55. The Patent Office initially rejected all the claims of the '749 application on prior art  
28 and other grounds of patentability in an office action mailed March 22, 1993. The Patent Office





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1 revive their '505 application by filing a formal petition to revive the '505 application. In that  
2 petition, the applicants misrepresented the fact concerning their prior intentional abandonment of  
3 the '505 application and claimed that they "unintentionally" failed to respond to the Patent Office.  
4 The applicants stated that "[t]he abandonment occurred as a result of the oversight of Applicants  
5 representative and was not intended by Applicants."

6 64. As set forth above, the applicants' claim of unintentional abandonment of the '505  
7 was false. Gen-Probe is informed and believes, and based thereon alleges, that the applicants'  
8 failure to respond to the Patent Office's rejection of the claims of '505 application directed to the  
9 claimed invention of a method of nuclei acid amplification was intentional. Indeed, the applicants'  
10 intentional decision not to respond to the '505 office action was consistent with and driven by  
11 applicants' underlying decision to abandon the invention claimed in the '505 application.

12 65. On October 27, 1994, the Patent Office rendered a decision denying the applicants'  
13 petition to revive the '505 application. As the Patent Office explained, the '505 application became  
14 abandoned on February 6, 1993, when the applicants failed to respond to the office action of  
15 November 5, 1992. Because the petition to revive the '505 application was filed more than one  
16 year after the '505 application became abandoned, the petition was barred under 37 C.F.R.  
17 1.137(b). Accordingly, the Patent Office refused to revive the '505 application under 37 C.F.R.  
18 1.137(b).

19 66. The Patent Office informed the applicants that they might be able to revive the '505  
20 application under the provisions of 37 C.F.R. 1.137(a). However, the Patent Office explained that  
21 "in view of the fact that this case has been abandoned for an inordinate period of time, petitioner  
22 must show diligence between the time of becoming aware of the abandonment of the above-  
23 identified application and the filing of a petition to revive."

24 67. The applicants declined to seek relief pursuant to 37 C.F.R. 1.137(a), thereby  
25 acquiescing to the Patent Office's determination that the '505 patent was abandoned on February 6,  
26 1993.

27 68. Concurrent with their ultimately unsuccessful effort to revive the '505 application,  
28 on May 3, 1994, the applicants filed a new original application that the Patent Office designated as





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1 would be processed with a filing date of May 3, 1994.

2 72. The Patent Office decisions denying the applicants' petitions to revive the '505  
3 application and to treat the '080 application as a continuation of the '505 created significant, indeed  
4 insurmountable, impediments to the applicants' desire to recant and reverse their earlier  
5 abandonment of the '505 application and the alleged invention consisting of the amplification  
6 method presented therein. Among other problems raised by those decisions, the applicants knew  
7 that unless they could manipulate the priority to which the '080 application was entitled, their own  
8 prior publications would constitute statutory bars to patentability.

9 **APPLICANT'S EFFORTS TO FRAUDULENTLY MANUFACTURE CLAIMS OF PRIORITY**  
10 **FOR THE '080 APPLICATION**

11 73. In light of the foregoing fatal impediments to patentability of the method claims  
12 presented in the '080 application, the applicants then proceeded to manufacture a scheme to  
13 undermine the Patent Office decisions denying their ability to claim priority for the '080 application  
14 back through the '505 application. As the first step in that scheme, on December 5, 1995, the  
15 applicants submitted a preliminary amendment in the '080 application in which they claimed, for  
16 the first time, that the '080 application was a divisional application to the '657 application that the  
17 applicants filed on March 8, 1995 to pursue the instrument claims and invention first claimed in the  
18 '468 application, as alleged in paragraph 60 of this Amended Complaint.

19 74. The applicants' efforts regarding and claim of priority of the '080 application to the  
20 '657 application were improper for several reasons. First, as indicated above, the applicants had  
21 previously elected to pursue only the instrument claims in the '657 application. As such, and  
22 without prior disclosure to or permission from the Patent Office, the applicants impermissibly  
23 "shift" their method claims back to the claim 24 of the '920 application, and subject to the  
24 restriction of July 20, 1990, in that application. As noted hereinabove, the applicants originally  
25 filed the chain of applications that included the '657 application in order to prosecute the claims  
26 directed to an invention regarding an instrument for performing assays for target polynucleotides.  
27 Second, the applicants' efforts to claim that the '080 application was a divisional application of the  
28 '657 application was additionally defective because the specification and claims of the '080 patent

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1 are different from and not supported by the specification and claims of the '657 application.

2 75. However, in applicants' zeal to implement their inequitable scheme to overcome the  
3 Patent Office determination that the claims of the '080 application were only entitled to claim  
4 priority as of May 3, 1994, the applicants overlooked an even more significant defect in their effort  
5 to claim priority for the '080 application to the '657 application. Under the patent laws and  
6 regulations, an application is only entitled to claim priority to a prior application if such application  
7 was co-pending at some point in the "life" of the two applications. Yet, with respect to the  
8 applicants' scheme to advance the priority of the '080 application, their claim to priority of the '080  
9 application to the '657 application violated this requirement of co-pendency because the applicants  
10 did not file the '657 application until March 8, 1995, nearly one year after the applicants filed the  
11 '080 application! The applicants failed to advise the Patent Office of this lack of co-pendency in  
12 their December 5, 1995, preliminary amendment. Gen-Probe is informed and believes, and based  
13 thereon alleges, that the applicants knew that the representation that the '080 application was a  
14 divisional of the '657 application was improper, and that the applicants made this representation  
15 with the intent of deceiving and misleading the Patent Office.

16 **APPLICANTS' MISREPRESENTATIONS ABOUT MULLIS, U.S. PATENT NO. 4,683,202.**

17 76. Despite their intentional failure to disclose the fatal defect in their claim of priority  
18 in the '080 application, the applicants continued to prosecute the claims of that application. During  
19 the course of that continued prosecution of the '080 application, the Patent Office rejected  
20 applicants' proposed claims to a method of nucleic acid amplification on the grounds of the  
21 disclosure of prior art that included the Mullis patent (U.S. Patent 4,683,202). In response, the  
22 applicants argued that the prior art did not teach or disclose purification of a target nucleic acid  
23 prior to amplification, yet, that argument was false. Specifically, in their December 5, 1995  
24 Preliminary Amendment, the applicants made the following statements regarding the Mullis patent:

25 Applicants submit the Examiner's conclusions is the product of an  
26 improper picking and choosing of selective disclosure from the  
27 cited references to obtain Applicants' invention and that when the  
28 references are considered for all that they teach the references do  
not disclose or suggest Applicants' invention. For example, while  
it is true that Mullis (U.S. No. 4,683,202) discloses DNA

1 amplification and some improved sensitivity and ability to isolate  
2 specific nucleoside sequences, Mullis also teaches away from  
Applicants' invention. Specifically, Mullis teaches:

3 The present invention obviates the need for  
4 extensive purification of the product from a  
5 complicated biological mixture.

6 (Col. 2, lines 32-34). Mullis reaffirmed this teaching later in the  
disclosure:

7 *It is not necessary that the sequence to be*  
8 *amplified be present initially in a pure form; it*  
9 *may be a minor fraction of a complex mixture ...*  
10 *or a portion of a nucleic acid sequence due to a*  
11 *particular microorganism which organism might*  
*constitute only a very minor fraction of a*  
*particular biological sample.*

12 (Col. 5, lines 49-56). Plainly, Mullis teaches that the amplification  
13 method of his invention does not include purification before  
14 amplification and, in fact, does not require purification. Thus,  
Mullis teaches away from Applicants' invention.

15 12/5/95 Preliminary Amendment at p. 16 [emphasis added]. The applicants repeated this  
16 representation to the Patent Office regarding the teachings of Mullis in the Amendment filed on  
17 October 18, 1996, at pp. 11-12.

18 77. The paragraph cited by the applicants from the Mullis patent reads in whole:

19 Any source of nucleic acid, in *purified* or nonpurified form, can be  
20 utilized as the starting nucleic acid or acids, provided it contains or  
21 is suspected of containing the specific nucleic acid sequence  
22 desired. Thus, the process may employ, for example, DNA or  
23 RNA, including *messenger RNA*, which DNA or RNA may be  
24 single stranded or double stranded. In addition, a DNA-RNA  
25 hybrid which contains one strand of each may be utilized. A  
26 mixture of any of these nucleic acids may also be employed, or *the*  
27 *nucleic acid produced from a previous amplification reaction*  
28 *herein using the same or different primers may be so utilized. The*  
*specific nucleic acid sequence to be amplified may be only a*  
*fraction of a larger molecule or can be present initially as a*  
*discrete molecule, so that the specific sequence constitutes the*  
*entire nucleic acid. It is not necessary that the sequence to be*  
*amplified be present initially in a pure form; it may be a minor*  
*fraction of a complex mixture, such as a portion of the .beta.-*  
*globin gene contained in whole human DNA or a portion of*

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1 nucleic acid sequence due to a particular microorganism which  
2 organism might constitute only a very minor fraction of a  
3 particular biological sample. The starting nucleic acid may contain  
4 more than one desired specific nucleic acid sequence which may  
5 be the same or different. Therefore, the present process is useful  
6 not only for producing large amounts of one specific nucleic acid  
sequence, but also for amplifying simultaneously more than one  
different specific nucleic acid sequence located on the same or  
different nucleic acid molecules.

(Col. 5, lines 34-63), emphasis added, underlined is the portion selectively cited by the applicants).

Thus, contrary to the applicants' representation to the Patent Office, the omitted portion of the paragraph cited by the applicants expressly teaches that ***purification can and should be used*** with the amplification invention, thereby validating the Examiner's rejection.

78. In addition to the excluded portion of the paragraph of the Mullis patent, the very next paragraph in the Mullis patent states:

The nucleic acid or acids may be obtained from any source, for example, from plasmids such as pBR322, from cloned DNA or RNA, or from natural DNA or RNA from any source, including bacteria, yeast, viruses, and higher organisms such as plants or animals. ***DNA or RNA may be extracted from blood, tissue material such as chorionic villi or amniotic cells by a variety of techniques such as that described by Maniatis et al., Molecular Cloning A Laboratory Manual (New York: Cold Spring Harbor Laboratory, 1982), pp. 280-281.***

(Col. 5, line 64-col. 6, line 6 [emphasis added]). Maniatis, et al., is a methods manual that teaches a variety of techniques for purifying RNA or DNA from blood, tissue or other cellular material. At pages 197-198 of Maniatis, et al., this reference teaches the purification of mRNA on a solid support using a probe. Thus, the very next paragraph of the Mullis patent following the selective citation by the applicants incorporates a disclosure of ***how*** to purify a sample prior to amplification. Gen-Probe is informed and believes, and based thereon alleges, that the applicants' knowingly and intentionally misrepresented the teachings of the Mullis reference to the United States Patent and Trademark Office. The applicants' selective removal of the first half of the cited paragraph that fully supported the Examiner's rejection based on Mullis and the following paragraph's implicit teaching of how to purify a sample prior to amplification evidence the knowing and intentional

1 nature of the applicants' misrepresentation of the Mullis reference.

2 **APPLICANTS' MISREPRESENTATIONS IN THE REQUEST FOR CERTIFICATE OF CORRECTION**  
3 **FILED FOR THE '338 PATENT**

4 79. On December 14, 1998, the applicants submitted a Request for Certificate of  
5 Correction for the '338 patent. Gen-Probe is further informed and believes, and based thereon  
6 alleges, that in this Request for Certificate of Correction the applicants represented to the U.S.  
7 Patent and Trademark Office that the '505 application was unintentionally abandoned.

8 80. Gen-Probe is informed and believes, and based thereon alleges, that the applicants  
9 made this representation knowing that the true facts were that the '505 application was intentionally  
10 abandoned.

11 81. In the December 14, 1998, Request for Certificate of Correction for the '338 patent,  
12 the applicants identified a fatal defect in the claimed priority for the '338 patent involving patent  
13 application Serial No. 07/648,468, and patent application Serial No. 07/136,920. By the December  
14 14, 1998, Request for Certificate of Correction, the applicants attempted to cure that fatal defect by,  
15 in part, representing to the Patent Office that the applicants did not discover the fatal priority defect  
16 prior to the issuance of the '338 patent.

17 82. The applicants also represented in the Request for Certificate of Correction for the  
18 '338 patent that the mistakes for which correction was sought were of minor character, and resulted  
19 from errors made in good faith by the applicants.

20 83. Gen-Probe is informed and believes, and based thereon alleges, that through the  
21 aforementioned Certificate of Correction, the applicants knowingly and intentionally  
22 misrepresented its knowledge regarding this priority defect with the intent of deceiving the U.S.  
23 Patent and Trademark Office. In truth, the applicants were aware of the defect in its claim of  
24 priority for the '338 patent well before the issuance of the '338 patent. In addition, Gen-Probe is  
25 informed and believes, and based thereon alleges, that the applicants knew that the mistakes for  
26 which correction was sought were not of minor character, and did not resulted from errors made in  
27 good faith by the applicants, and intentionally misrepresented this to the Patent Office.

28 84. The applicants further represented in the Request for Certificate of Correction for

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1 the '338 patent that the '338 patent was a continuation of the '826 application. However, the '338  
2 patent could not be a continuation of the '826 application, because the disclosure of the '338 patent  
3 was not identical to the disclosure of the '826 application.

4 85. Gen-Probe is informed and believes, and based thereon alleges, that the applicants  
5 knew that the '338 patent could not be a continuation of the '826 application, and that through the  
6 aforementioned Certificate of Correction, the applicants knowingly and intentionally  
7 misrepresented its knowledge with the intent of deceiving the U.S. Patent and Trademark Office.

8 **APPLICANTS' MISREPRESENTATION IN THEIR PETITION UNDER 37 C.F.R. §1.182**

9 86. On December 14, 1998, the applicants filed a petition with the Patent Office under  
10 37 C.F.R. § 1.182 to amend the claimed priority stated in application Serial No. 08/124,826 (the  
11 "'826 application") so as to attempt to cure further fatal defects in the priority claim for the '338  
12 patent. At the time of such petition, however, the applicants had previously intentionally  
13 abandoned the '826 application.

14 87. In order to overcome the impediment to its effort to cure the fatal defect in the  
15 claim of priority for the '338 patent arising in the '826 application, the applicants argued in its  
16 petition to amend the '826 application that an intentionally abandoned application could be  
17 amended after abandonment. Gen-Probe is informed and believes, and based thereon alleges, that  
18 the applicants misrepresented legal authority to the U.S. Patent and Trademark Office. Gen-Probe is  
19 informed and believes, and based thereon alleges, that the applicants' knew that the legal authority  
20 it presented to the Patent Office to support its petition to amend the '826 application and cure the  
21 otherwise fatal priority defect in the '338 patent did not stand for the proffered proposition and that  
22 the applicants knowingly misrepresented this legal authority to the U.S. Patent and Trademark  
23 Office with the intent to deceive the Patent Office.

24 **APPLICANTS' FAILURE TO DISCLOSE ALL ART KNOWN TO IT DURING THE PROSECUTION**  
25 **OF THE '338 PATENT**

26 88. During the course of its prosecution of the claims that ultimately issued in the '338  
27 patent, the applicants concurrently presented counterpart patent applications and patent claims to  
28 international and foreign patent offices. During the course of the examination and prosecution of



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- 1                   b.     That the claims of the '338 patent are invalid;
- 2                   c.     That the claims of the '338 patent are unenforceable; and
- 3                   d.     Of Gen-Probe's rights and obligations under the License;
- 4           2.     For a preliminary and permanent injunction enjoining and restraining defendant, its
- 5     respective officers, agents, servants, employees and attorneys, and all persons acting in concert
- 6     with them, and each of them:
- 7                   a.     From making any claims to any person or entity that Gen-Probe's products
- 8     infringe the '338 patent;
- 9                   b.     From interfering with, or threatening to interfere with the manufacture, sale,
- 10    license, or use of Gen-Probe's products by Gen-Probe, its allied parties, distributors, customers,
- 11    licensees, successors or assigns, and others; and
- 12                   c.     From instituting or prosecuting any lawsuit or proceeding, placing in issue
- 13    the right of Gen-Probe, its allied parties, distributors, customers, licensees, successors or assigns,
- 14    and others to make, use or sell Gen-Probe's products;
- 15           3.     For recovery of Gen-Probe's damages, as proven at time of trial, and restitution of
- 16    any sums by which Vysis has been unjustly enriched;
- 17           4.     For recovery of Gen-Probe's attorneys' fees and costs of suit incurred herein; and
- 18           5.     For such other and further relief as the Court may deem just and proper.

19    Dated: January \_\_, 2001                               STEPHEN P. SWINTON  
20   COOLEY GODWARD LLP

21   DOUGLAS E. OLSON  
22   BROBECK PHLEGER & HARRISON LLP

23   R. WILLIAM BOWEN, JR.  
24   GEN-PROBE, INC.

25

26   By: \_\_\_\_\_

27   Stephen P. Swinton

28   Attorneys for Plaintiff  
   GEN-PROBE INCORPORATED  
   CIVIL CASE NO. 99CV2668H AJB





**EXHIBIT 1:** *Symbol Technologies, Inc. v. Lemelson Medical, Education & Research Foundation, Limited Partnership*, 2000 WL 1300430 (Fed. Cir. Sept. 1, 2000).

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R. WILLIAM BOWEN, JR.  
GEN-PROBE INCORPORATED

By: Stephen P. Swinton  
Stephen P. Swinton

Attorneys for Plaintiff  
GEN-PROBE INCORPORATED

**00000000000000000000**



NOTE: THIS OPINION WILL NOT BE  
PUBLISHED IN A PRINTED VOLUME. THE  
DISPOSITION WILL APPEAR IN A REPORTER  
TABLE.

**SYMBOL TECHNOLOGIES, INC., Accu-Sort  
Systems, Inc., Intermec Technologies  
Corporation, Metrologic Instruments, Inc., PSC  
Inc., Teklogix Corporation,  
Zebra Technologies Corporation, and Cognex  
Corporation, Plaintiffs-Petitioners,**

**No. 626.**

Sept. 1, 2000.

### On Petition for Permission to Appeal.

Before MICHEL, RADER, and SCHALL, Circuit  
Judges.

## ORDER

**MICHEL, Circuit Judge.**

**\*1 Symbol Technologies, Inc. et al. (Symbol) petition for permission to appeal, pursuant to 28 U.S.C. § 1292(b), (c)(1), an order certified by the United States District Court for the District of Nevada. Lemelson Medical, Education, & Research Foundation, Limited Partnership (Lemelson) opposes. National Retail Federation moves for leave to file an amicus curiae brief in support of granting the petition, with brief attached. Lemelson opposes.**

Briefly, this declaratory judgment action involves Lemelson patents related to bar code technology. The patents, which contain identical written

descriptions and drawings, are based on a chain of continuing and divisional applications and may be entitled to a priority date in the mid 1950s. Lemelson moved to dismiss Symbol's defense, asserted in the fourth count of Symbol's complaint, that the equitable doctrine of laches in patent prosecution could be applied. The district court granted the motion to dismiss stating:

[In Ford v. the Honorable Lloyd D. George ... held that "Lemelson's use of the continuation applications process may have exploited an open area of patent practice, [but] the court should not intervene in equity to regulate what Congress has not." It is therefor improper to introduce the equitable doctrine of laches into the statutory scheme of continuation practice.

The district court subsequently certified its order dismissing Symbol's "laches in prosecution" claim as involving a controlling question of law as to which there was a substantial ground for difference of opinion and that an immediate appeal from such order could materially advance the ultimate termination of the litigation. [FN\*]

**FN\* Symbol asserts that the controlling question of law is:**

As a matter of law, can the equitable doctrine of laches ever apply to bar enforcement of patent claims which were first presented to the Patent Office for examination after an unreasonable and unexplained delay that causes injury to an alleged infringer and others?

Symbol states that this court has not definitively determined whether laches in prosecution can be a defense to an infringement action. Symbol also states that Lemelson has sued "hundreds of defendants" based on its bar code patents. Symbol and the amicus forcefully urge the court to grant Symbol's petition.

This court has complete discretion in determining whether to grant or deny a petition for permission to appeal. In re Convertible Rowing Exerciser Patent Litigation, 903 F.2d 822 (Fed.Cir.1990). We determine in our discretion to grant Symbol's petition, in part because the issue affects not only this case, but many other cases as well.

**Accordingly,**

**IT IS ORDERED THAT:**

[illegible]

(2) National Retail Federation's motion for leave to file an amicus brief in support of the petition is granted.

END OF DOCUMENT

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18 Facsimile: (858) 410-8637

19 Attorneys for Plaintiff,  
20 GEN-PROBE INCORPORATED

21 UNITED STATES DISTRICT COURT  
22 SOUTHERN DISTRICT OF CALIFORNIA

23 GEN-PROBE INCORPORATED,

24 Plaintiff,

25 v.

26 VYSIS, INC.,

27 Defendant.

No. 99cv2668 H (AJB)

**PROOF OF PERSONAL SERVICE**

Date: February 20, 2001  
Time: 10:30 a.m.  
Dept.: Courtroom 1

**PROOF OF PERSONAL SERVICE**

I, \_\_\_\_\_, hereby declare:

I am employed in the City of San Diego, County of San Diego, California; I am over the age of eighteen years and not a party to the within action; my business address is Express Network, 401 West A Street, Suite 190, San Diego, California 92101.

On January 19, 2001, I served the within NOTICE OF MOTION AND MOTION OF GEN-PROBE INCORPORATED FOR LEAVE TO FILE SECOND AMENDED COMPLAINT; MEMORANDUM POINTS AND AUTHORITIES IN SUPPORT IN SUPPORT OF GEN-PROBE INCORPORATED'S MOTION FOR LEAVE TO FILE A SECOND AMENDED COMPLAINT; DECLARATION OF STEPHEN P. SWINTON IN SUPPORT OF GEN-PROBE INCORPORATED'S MOTION FOR LEAVE TO FILE SECOND AMENDED COMPLAINT; NOTICE OF LODGMENT OF CASE AUTHORITY NOT IN OFFICIAL REPORTER SYSTEM IN SUPPORT OF GEN-PROBE INCORPORATED'S MOTION FOR LEAVE TO FILE SECOND AMENDED COMPLAINT on the interested parties in this action by personally hand delivering a copy of said document(s) to the address(es) listed below:

John H. L'Estrange, Jr. Esq.  
Wright and L'Estrange  
701 B Street, Suite 1550  
San Diego, CA 92101  
Tel: (619) 231-4844  
Fax: (619) 231-6710  
**Attorneys for Vysis, Inc.**

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this declaration was executed on January 19, 2001.

\_\_\_\_\_  
(signature)

\_\_\_\_\_  
(print name)

**STEPHEN P. SWINTON (106398)**  
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**Attorneys for Plaintiff,  
GEN-PROBE INCORPORATED**

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,

Plaintiff,

**v.**

VYSIS, INC.,

**Defendant.**

No. 99cv2668 H (AJB)

## PROOF OF SERVICE

Date: February 20, 2001  
Time: 10:30 a.m.  
Dept.: Courtroom 1



**PROOF OF SERVICE (FEDERAL EXPRESS)**

I, Alison J. Lyman, hereby declare:

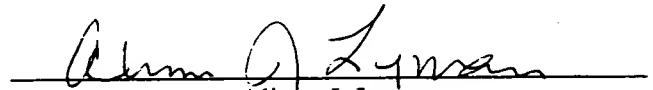
I am employed in the City of San Diego, County of San Diego, California in the office of a member of the bar of the court in which the within action is pending at whose direction the following service was made. I am over the age of eighteen years and not a party to the within action. My business address is Cooley Godward LLP, 4365 Executive Drive, Suite 1100, San Diego, California 92121-2128. I am personally and readily familiar with the business practice of Cooley Godward LLP for collection and processing of notices and other papers to be sent by overnight delivery service by Federal Express. Pursuant to that business practice, envelopes and packages are placed for collection at designated stations and in the ordinary course of business are that same day deposited in a box or other facility regularly maintained by such express service carrier or delivered to an authorized courier or driver authorized by such express service carrier to receive documents, in an envelope or package designated by such express service carrier, with delivery fees paid or provided for.

On January 19, 2001, I served: NOTICE OF MOTION AND MOTION OF GEN-PROBE INCORPORATED FOR LEAVE TO FILE SECOND AMENDED COMPLAINT; MEMORANDUM POINTS AND AUTHORITIES IN SUPPORT IN SUPPORT OF GEN-PROBE INCORPORATED'S MOTION FOR LEAVE TO FILE A SECOND AMENDED COMPLAINT ; DECLARATION OF STEPHEN P. SWINTON IN SUPPORT OF GEN-PROBE INCORPORATED'S MOTION FOR LEAVE TO FILE SECOND AMENDED COMPLAINT; NOTICE OF LODGMENT OF CASE AUTHORITY NOT IN OFFICIAL REPORTER SYSTEM IN SUPPORT OF GEN-PROBE INCORPORATED'S MOTION FOR LEAVE TO FILE SECOND AMENDED COMPLAINT on the interested parties in this action by placing a true copy thereof, on the above date, enclosed in a sealed envelope, at a station designated for collection and processing of envelopes and packages for overnight delivery service by Federal Express as part of the ordinary business practice of Cooley Godward LLP described above, addressed as follows:

1 Charles E. Lipsey, Esq.  
2 Finnegan, Henderson, Farabow, et al.  
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4 Washington, DC 20005-3315  
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7 **Attorneys for Vysis, Inc.**

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Tel: (650) 849-6600  
Fax: (650) 849-6666  
**Attorneys for Vysis, Inc.**

8 I declare under penalty of perjury under the laws of the State of California that the  
9 foregoing is true and correct, and that this declaration was executed on January 19, 2001, at  
10 San Diego, California.

11   
12 Alison J. Lyman

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